

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| WARNER CHILCOTT COMPANY, LLC, | : | |
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| Plaintiff(s), | : | Civil Action No. 11-6844 (JAP) |
| | : | |
| v. | : | |
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| MYLAN INC., et al. | : | |
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| Defendant(s). | : | |
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| WARNER CHILCOTT COMPANY, LLC, | : | |
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| Plaintiff(s), | : | Civil Action No. 11-7228 (JAP) |
| | : | |
| v. | : | |
| | : | |
| LUPIN LTD., et al., | : | OPINION |
| | : | |
| Defendant(s). | : | |
| _____ | : | |

PISANO, District Judge.

This is a Hatch-Waxman patent infringement action in which Plaintiff Warner Chilcott Company LLC (“Plaintiff “or “Warner”) alleges that Mylan, Inc., Mylan Pharmaceuticals Inc. and Famy Care Ltd. (collectively, “Mylan”) and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”; and with Mylan, “Defendants”) have infringed U.S. Patent 6,667,050 (the “’050 patent”). Presently before the Court is the parties’ request for claim construction. The Court held a *Markman* hearing on June 12, 2013. This Opinion addresses the proper construction of the disputed claim terms.

I. BACKGROUND

The '050 patent issued from U.S. Patent Application No. 09/879,028, filed on June 21, 2001. It is entitled "Chewable Oral Contraceptive" and contains 60 claims, 36 of which are asserted in these actions. The asserted claims are directed to chewable, palatable oral contraceptive tablets and methods of female oral contraception. The drug product underlying the dispute is the oral contraceptive Generess FE, which Plaintiff alleges is covered by the '050 patent. Mylan and Lupin have filed abbreviated new drug applications ("ANDAs") seeking to market chewable oral contraceptive products that Plaintiff contends infringe the '050 patent.

The parties have identified certain terms in need of construction. They have agreed on the construction of three of those terms, and the agreed constructions are set forth in Exhibit B of the parties joint claim construction statement. *See* D.I. 53 in Civil Action No. 11-6844. The following three term remain in dispute: "tablet"; "at least one of a flavor agent, a sweetener, and a color agent"; and "has a hardness sufficient for blister packaging." The Court construes these below.

II. LEGAL STANDARDS

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves ... to define the scope of the

patented invention”). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff’d* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), therefore, it is “[t]he duty of the trial judge ... to determine the meaning of the claims at issue,” *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their “ordinary and customary meaning,” which is defined as “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1312–13 (citations omitted). In this regard, the Federal Circuit has noted that

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of “the words of the claims themselves, the remainder of the specification, [and] the prosecution history,” *id.* at 1314, and

extrinsic evidence “concerning relevant scientific principles, the meaning of technical terms, and the state of the art,” *id.*

When considering the intrinsic evidence, the court’s focus must begin and remain on the language of the claims, “for it is that language that the patentee chose to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’ ” *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. § 112, ¶ 2). The specification is often the best guide to the meaning of a disputed term. *Honeywell Int’l v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). It is improper, however, to import limitations from the specification into the claims. *Seachange Int’l v. C-COR Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may also consider as intrinsic evidence a patent’s prosecution history, which is evidence of “how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Phillips*, 415 F.3d at 1317.

While a court is permitted to consider extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 (“We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms.”). While “extrinsic evidence may be useful to the court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless

considered in the context of the intrinsic evidence.” Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322–23.

III. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

“*tablet*”

This term appears in asserted claims 1–36 of the ‘050 patent. Claim 1 is representative and reads as follows: “A chewable, palatable oral contraceptive tablet, comprising an oral contraceptive agent, a chewable carrier suitable for human consumption, wherein the contraceptive tablet is chewable and palatable and does not contain a ferrocene compound.” Multiple constructions have been proposed for the term “tablet.” Plaintiff originally asserted that this term should be construed as “a solid pharmaceutical dosage form that is manufactured by standard pharmaceutical techniques, i.e., compression or molding.” However, moments before the filing of this Opinion, the Court received a letter from Plaintiff stating that, based upon its review of the *Markman* hearing transcript, Plaintiff was offering a new proposed construction, specifically, “A solid oral pharmaceutical dosage form that does not include capsules, gums or film/paper-type dosage forms.” D.I. 85. Lupin proposes that the Court construe the term to mean “a solid dosage form containing an active agent or agents.” Mylan argues that the proper construction is “a solid oral dosage form that does not include capsules.”

As noted earlier, the purpose of claim construction is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim construction must be undertaken by a court when and only when “the parties raise an *actual dispute* regarding the proper scope of these claims.” *O2 Micro Int’l*

Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360, 1362 (Fed. Cir. 2008) (emphasis supplied). Here, despite a careful reading of the parties’ submissions as well as questioning counsel at oral argument, it is still unclear to the Court exactly what the actual dispute is between the parties regarding this claim term. While each party has taken issue with the others’ proposed constructions¹ and has pointed to alleged flaws in the each of the proffered constructions, no party has been able to adequately articulate how, based upon the claim term “tablet,” the meaning or proper scope of any of the asserted claims is in dispute. At the outset it seemed that each party in this case was concerned that the others’ proposed definitions could encompass other pharmaceutical dosage forms not typically considered to be a “tablet”; however, it was made clear at oral argument that all parties agree that “tablet” does not include other dosage forms such as liquids, capsules, films and gums. *See, e.g.*, Markman Hearing Transcript at 22-23.

A court is not required to construe a claim term where there is not an actual dispute with respect to that term. *See O2 Micro*, 521 F.3d at 1362 (“[D]istrict courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims”); *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir.1997) (“Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.”). A threshold question to be addressed as part of a court’s duty to undertake claim construction is whether and to what extent construction is even necessary. *National Oilwell Varco, L.P. v. Auto-Drill, Inc.*, No. 09–85, 2011 WL 3648532, at *6 (E.D. Tex. Aug. 16, 2011) (noting that “[w]hile it is

¹ With the exception of Plaintiff’s newly proffered construction, to which Defendants have not, to date, responded.

a district court's duty is to construe the claims, part of this duty is to determine the extent [to which] construction is even necessary.) Here, the parties have not established that construction of the term “tablet” is necessary. As such, the Court declines to adopt any of the parties’ proposed constructions at this time, and the term’s plain and ordinary meaning shall govern.

“hardness sufficient for blister packaging”

This term appears in asserted claims 16 and 34 of the ‘050 patent. Claim 16 is reads as follows: “The tablet of claim 1, wherein the tablet has a hardness sufficient for blister packaging.” (Claim 1 is recited above.) Claim 34 relates to a method claim and reads: “The method of claim 19, wherein the tablet has a hardness sufficient for blister packaging.” The method of claim 19 is as follows:

A method of human female oral contraception, the method comprising providing a chewable, palatable oral contraceptive tablet comprising a contraceptively effective amount of an oral contraceptive agent, and a chewable carrier suitable for human consumption, and does not contain a ferrocene compound, and administering the tablet to a human female.

Plaintiff asserts that the Court should construe the term “hardness sufficient for blister packaging” to mean “any hardness that allows for the formation of tablets that are palatable and chewable and that allows the tablet to be administered from the blister packaging.” Defendants contend that no construction is necessary and the term’s plain meaning should apply.

In support of their proposed construction, Plaintiff relies primarily upon the ‘050 patent specification. With respect to the hardness of the claimed tablet, the specification provides, for example:

The hardness of the tablet may be any hardness that allows for tablet formation and that is still palatable and chewable. One aspect of the invention includes having a hardness sufficient for blister packaging while still remaining palatable and chewable.

'050 patent, col. 8, lines 1-6. Plaintiff asserts that its construction provides the upper and lower limits to the allowable “hardness” of the invention. Defendants object to construing this claim at all, arguing that its ordinary and customary meaning as understood by one in the art is apparent.

Here, again, the precise nature of the dispute between the parties over the claim term has not been made clear by the parties. Indeed, Lupin admits that the “common ground” between the parties’ positions is “substantial.” Lupin Opening Br. at 11. It appears that Defendants’ primary objection to Plaintiff’s proposed construction is that it reiterates other limitations already in the claim – not necessarily that it is substantively incorrect.

As with the disputed claim term above, the Court is not convinced that construction of this term is necessary and agrees with Defendants that its ordinary meaning would be apparent to a skilled artisan. Consequently, for the disputed term “hardness sufficient for blister packaging,” the plain and ordinary meaning of the term shall apply.

“at least one of a flavor agent, a sweetener, and a color agent”

This term appears in claims 14 and 32 of the '050 patent. Claim 14 reads: “the tablet of claim 13, further comprising at least one of a flavor agent, a sweetener, and a color agent.” Claim 32 is similar, and reads “the method of claim 31, wherein the table further comprises at least one of a flavor agent, a sweetener, and a color agent.” Interestingly, all three parties argue for the “plain meaning” of the term, but have proposed different constructions. Plaintiff proposes that the term be construed as “the tablet comprises at least one flavor agent, at least

one sweetener, and at least one color agent.” Lupin contends the term means “at least one of a flavor agent, a sweetener, and a color agent.” Mylan’s proposal is “one or more of a flavor agent, a sweetener, or a color agent. The dispute among the parties centers on whether the term should be construed conjunctively or disjunctively, *i.e.*, whether the claims require that all three of these agents be in the tablet, or whether just one of the three is required. Plaintiff seeks the narrower, conjunctive construction, while Defendants advance the broader, disjunctive construction.

The Federal Circuit has held that use by a patentee of “[t]he phrase ‘at least one of’ preced[ing] a series of categories of criteria, and ... the term ‘and’ to separate the categories of criteria,” connotes a conjunctive list. *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 886 (Fed. Cir. 2004). The Federal Circuit applied standard grammatical principles in so holding:

A common treatise on grammar teaches that “an article of a preposition applying to all the members of the series must either be used only before the first term or else be repeated before each term.” William Strunk, Jr. & E.B. White, *The Elements of Style* 27 (4th ed. 2000). Thus, “[i]n spring, summer, or winter” means “in spring, in summer, or in winter.” *Id.* Applying this grammatical principle here, the phrase “at least one of” modifies each member of the list, *i.e.*, each category in the list.

Id.

Thus, under *SuperGuide* and the rules of grammar applied by the circuit court, the plain meaning of the disputed term here is clear. The disputed term should be construed to require at least one flavor agent, at least one sweetener, and at least one color agent. It is to be construed conjunctively as it uses the word “and” instead of “or.”

The Court finds Defendants’ arguments for a disjunctive construction to be unavailing. Defendants rely largely upon the assertion that none of the examples in the specification

include at least one flavor agent, at least one sweetener, and at least one color agent.

However, Defendants point to no requirement that a patentee disclose by example every conceivable embodiment of the invention. Indeed, case law supports the contrary conclusion. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001) (“Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.”). Moreover, at least one Example in the specification does appear to contemplate an embodiment that includes all three additives. *See, e.g.*, Example 1 (listing a sweetener, a flavor agent and stating that “optional ingredients” may be used, among which is a coloring agent).

Consequently, the Court construes the term “at least one of a flavor agent, a sweetener, and a color agent” to mean “the tablet comprises at least one flavor agent, at least one sweetener, and at least one color agent.”

IV. CONCLUSION

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: July 1, 2013